IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

TIFFANI BROWN,

Plaintiff,

Case No. 3:12 oe 40003

-vs-

MEMORANDUM OPINION

JANSSEN PHARMACEUTICALS, INC.

Defendant.

KATZ, J.

Tiffani Brown, who is a Tennessee resident, sued Ortho-McNeil Pharmaceutical, Inc. (now know as Janssen Pharmaceuticals, Inc.), Alza Corporation, Johnson & Johnson Pharmaceutical Research and Development, LLC (now known as Janssen Research & Development, LLC), and Johnson & Johnson in the Superior Court of Los Angeles County, California. Ms. Brown alleged that she had been prescribed the Ortho Evra® birth control patch which allegedly caused her to experience a bilateral pulmonary emboli.

On April 24, 2014, this Court granted Defendants' motion for summary judgment on Ms. Brown's failure to warn claim. The Defendants' motion for judgment on the pleadings was granted as to Ms. Brown's breach of implied warranty, breach of express warranty, and alleged violations of California's Business and Professions Code § 17200 and § 17500. (Doc. No. 21).

The Defendants have now moved for summary judgment on Ms. Brown's remaining claims of manufacturing defect, negligence, deceit by concealment, and negligent misrepresentation. (Doc. No. 23). Ms. Brown has filed a response (Doc. No. 24), and the Defendants have filed a reply. (Doc. No. 25). On September 23, 2014, the Court heard oral argument on the pending motion for summary judgment in this case and several other cases concerning the Ortho Evra® birth control patch.

I. Facts

Ms. Brown was first prescribed the Ortho Evra® birth control patch in December 2008, and she continued using the Ortho Evra® patch through February 2010. Ms. Brown received the prescription from her gynecologist, Dr. William Fitts, at the Dyersburg General Hospital in Dyersburg, Tennessee. Dr. Fitts is a licensed medical doctor and is Board certified in obstetrics and gynecology. The record reflects that at the time Dr. Fitts prescribed the Ortho Evra® patch, he was aware that Ortho Evra® exposes users to increased levels of estrogen, and that such exposure increases the risk of blood clots. Moreover, Dr. Fitts testified that notwithstanding these risks, he believed the Ortho Evra® patch was a reasonably safe method of birth control for Ms. Brown, and further believed that the risks to Ms. Brown were outweighed by the drug's benefits.

In February 2010, Ms. Brown suffered bilateral pulmonary emboli, allegedly as a result of using the Ortho Evra® patch. Ms. Brown filed her complaint on June 29, 2011. The case was subsequently removed to the United States District Court for the Central District of California before being transferred to the undersigned by the Judicial Panel on Multidistrict Litigation as related to the Ortho Evra® litigation. *In re Ortho Evra Prods. Liab. Litig.*, 1:06 cv 40000 MDL 1742 (N.D. Ohio).

II. Summary Judgment

Summary judgment is proper where "there is no genuine dispute as to any material fact" and the moving party "is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A party asserting a genuine issue of material fact must support the argument either by "citing to particular parts of materials in the record" or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible

evidence to support the fact." Fed. R. Civ. P. 56(c)(1). The Court views the facts in the record and reasonable inferences that can be drawn from those facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The Court does not weigh the evidence or determines the truth of any matter in dispute. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

The party requesting summary judgment bears an initial burden of demonstrating that no genuine issue of material fact exists, which the party must discharge by producing evidence to demonstrate the absence of a genuine issue of material fact or "by showing . . . that there is an absence of evidence to support the nonmoving party's case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986) (internal quotation marks omitted). If the moving party satisfies this burden, the nonmoving party "may not rest upon its . . . pleadings, but rather must set forth specific facts showing that there is a genuine issue for trial." *Moldowan v. City of Warren*, 578 F.3d 351, 374 (6th Cir. 2009) (citing Rule 56 and *Matsushita*, 475 U.S. at 586). The party opposing the summary judgment motion must present sufficient probative evidence supporting its claim that disputes over material facts remain; evidence that is "merely colorable" or "not significantly probative" is insufficient. *Anderson*, 477 U.S. at 248–52.

III. Manufacturing Defect

In order to prevail on a strict liability theory in Tennessee, Ms. Brown is required to provide proof that the Ortho Evra® patch, which allegedly caused her injuries, was "in a defective condition or unreasonably dangerous at the time it left the control of manufacturer or seller." Tenn. Code Ann. § 29–28–105; *Masters by Masters v. Rishton*, 863 S.W.2d 702, 706 (Tenn. Ct. App. 1992). Thus, a plaintiff must prove that the product was either defective or unreasonably

dangerous at the time it left the control of the manufacturer or seller, regardless of the legal theory relied upon. *Fulton v. Pfizer Hosp. Prods. Group, Inc.*, 872 S.W.2d 908, 911 (Tenn. Ct. App. 1993). Tennessee law defines a defective condition as "a condition of a product that renders it unsafe for normal or anticipatable handling and consumption." Tenn. Code Ann. § 29–28–102(2).

> A product is unreasonably dangerous if it is
>
> dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition.

Tenn. Code Ann. § 29–28–102(8). In determining whether a product is defective, "the state of scientific and technological knowledge available to the manufacturer or seller at the time the product was placed on the market . . . is applicable." Tenn. Code Ann. § 29–28–105(b). Consideration should also be given "to the customary designs, methods, standards and techniques of manufacturing, inspecting and testing by other manufacturers or sellers of similar products." *Id*.

An injury in and of itself is not proof of a defect and thereby does not raise any presumption of defectiveness. *Fulton*, 872 S.W.2d at 911. Thus, it is not enough to show that the product caused the plaintiff's injury or was involved in it. *Whaley v. Rheem Mfg. Co.*, 900 S.W.2d 296, 300 (Tenn. Ct. App. 1995). Rather, "[t]he burden is upon the plaintiff to 'show that there is something wrong with the product.'" *Fulton*, 872 S.W.2d at 911 (citation omitted). A departure from the required standard of care is not demonstrated by simply showing that there was a better, safer, or different design which might have avoided the injury. *Kerley v. Stanley Works*, 553

S.W.2d 80, 84 (Tenn. Ct. App. 1977). A manufacturer is not required to incorporate the ultimate safety features in a product. The manufacturer is not an insurer of its product. It is not required to design a perfect or accident-proof product. *Shoemake v. Omniquip Int'l, Inc.*, 152 S.W.3d 567, 573 (Tenn. Ct. App. 2003).

Ms. Brown has produced no evidence that the Ortho Evra® patches which she used were improperly manufactured or failed to comply with manufacturing procedures. Ms. Brown does not have any unused patches; no longer has the packaging materials from her patches; and does not know the lot number or numbers of the patches she received.

Ms. Brown responds to the Defendants' motion for summary judgment by simply stating she has "adequately pled [a] manufacturing defect." However, Defendants' motion is one for summary judgment and not failure to state a claim. As the nonmoving party, she may not rest on her pleadings and must set forth specific facts showing that there is a genuine issue for trial. *Moldowan*, 578 F.3d at 374. This she has not done. Because Ms. Brown has not provided evidence to show that there was something wrong with the patches she received, *Fulton*, 872 S.W.2d at 911, the Defendants are entitled to summary judgment on this issue.

IV. Negligence

Ms. Brown alleged that the Defendants "negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, marketed, labeled, packaged, prepared for use and sold ORTHO EVRA® and failed to adequately test and warn of the risks and dangers of ORTHO EVRA®." Although this quote establishes that Ms. Brown explicitly alleged that the Ortho Evera® patch was "negligently . . . designed," in her response to Defendants' motion for summary judgment she states that she "did not plead a cause

of action for negligent design." (Doc. No. 24, p. 7). Therefore, the Court finds that Ms. Brown has waived any negligent design claim against the Defendants.

V. Deceit by Concealment

Ms. Brown alleged that the Defendants engaged in deceit by concealment in violation of Cal. Stat. § 1709 and § 1710. Ms. Brown is a resident of Tennessee and received the Ortho Evera® patches from her physician in Tennessee. Ms. Brown has established no contact with California regarding her receipt of the Ortho Evera® patches. The state courts of California have held that these statutes do not apply to nonresidents arising from conduct occurring entirely outside California. *Norwest Mortg., Inc. v. Superior Court*, 85 Cal. Rptr. 2d 18, 23 (Cal. Ct. App. 1999). Because Ms. Brown is not a resident of California and did not receive the patches in California, she may not avail herself of these statutes. *Id*. Accordingly, the Defendants are entitled to summary judgment on this claim.

VI. Negligent Misrepresentation

Under Tennessee law, negligent misrepresentation has four elements:

> (1) the defendant is acting in the course of his business, profession or employment, or in a transaction in which he has a pecuniary (as opposed to gratuitous) interest; *and*
>
> (2) the defendant supplies faulty information meant to guide others in their business transaction; *and*
>
> (3) the defendant fails to exercise reasonable care in obtaining or communicating the information; *and*
>
> (4) the plaintiff justifiably relies upon the information.

Ritter v. Custom Chemicides, Inc., 912 S.W.2d 128, 130 (Tenn. 1995) (citations omitted, emphasis in original).

Ms. Brown admitted that she relied upon her doctor regarding information concerning the Ortho Evra® patches. Ms. Brown has provided no evidence that she relied upon any information supplied by the Defendants. Ms. Brown never communicated with the Defendants prior to being prescribed the patches. As the nonmoving party, Ms. Brown "may not rest upon [her] . . . pleadings, but rather must set forth specific facts showing that there is a genuine issue for trial." *Moldowan*, 578 F.3d at 374. Ms. Brown has failed to show that the Defendants supplied faulty information regarding the patches, that the Defendants failed to take reasonable care in obtaining or communicating the information regarding the patches, and that she relied on the information. *Ritter*, 912 S.W.2d at 130.

Furthermore, as the Court previously explained, Tennessee's learned intermediary doctrine applies where a physician is the intermediary between a defendant pharmaceutical, or other medical product manufacturer, and an injured patient. *Brown v. Janssen Pharm., Inc.*, No. 3:12 oe 40003, slip op. at 5 (N.D. Ohio Apr. 24, 2014) (citing *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 701 (Tenn. 2011)). A pharmaceutical manufacturer discharges its duty to warn by providing the physician with adequate warnings of the drug's risks. *Brown*, No. 3:12 oe 40003, slip op. at 5 (citing *Nye*, 347 S.W.3d at 701).

The Court has found that the Defendants provided adequate warnings sufficient to discharge their duty to warn. *Brown*, No. 3:12 oe 40003, slip op. at 6. Because the Defendants exercised reasonable care by communicating the risks involved with the Ortho Evra® patch to Ms. Brown's physician, and those warning were not faulty, Ms. Brown has not established a claim of negligent misrepresentation under Tennessee law. *Ritter*, 912 S.W.2d at 130. Therefore, the Defendants are entitled to judgment as a matter of law on this claim.

VII. Conclusion

Accordingly, Defendants' motion for summary judgment (Doc. No. 23) is granted.

IT IS SO ORDERED.

s/ *David A. Katz*
DAVID A. KATZ
U. S. DISTRICT JUDGE